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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/856,976	05/30/2001	Yoshiki Kuraya	0230-0158P	5295

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EXAMINER	
HELMER, GEORGIA L	
ART UNIT	PAPER NUMBER
1638	6

DATE MAILED: 04/23/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/856,976	Applicant(s) KURAYA ET AL.	
	Examiner Georgia Helmer	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 5/30/01 .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-7 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-7 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

Status of the application

1. Claims 1-7 are pending.

2. The preliminary amendment filed 5/30/01 has been entered.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

4. Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

5. In Claim 1,

- "based" on the function of Agrobacterium" is unclear. Does this mean physically based on the use of Ti plasmids, so that Ti plasmid components are incorporated? It is unclear whether or not an Agrobacterium vector is required. Or does it mean a system analogous to Agrobacterium transformation vectors? This language is further unclear because Agrobacterium has many functions and no particular function is specified.
- "The left border sequence" is unclear because which left border sequence and from where is not specified. This problem could be overcome by stating "the T-DNA left border sequence". All subsequent recitations of this language are also rejected.

- "such as" is indefinite because it can mean "for example" or "to result in". If "for example" is the intended meaning, then this language does not further limit the claim. To expedite prosecution, the Office interprets "such as" in this instance to mean "to result in".
- "reduce the possibility of integration" lacks a comparative basis. It is not possible to define the metes and bounds of these terms. Applicant discusses the term "reduce the possibility of integration" (specification, pg 10) and states that, compared to a non-modified vector, the frequency is low, the length of DNA is short, or that there is no integration. The definition needs to be a quantitative statement, such as for example, a percent reduction. What is the starting point for the possibility of the integration, and how does a "reduced" possibility relate to the starting point? All subsequent recitations of this language are also rejected.

In Claim 2,

- "the right border sequence" is unclear because which right border sequence and from where is not specified. This problem could be overcome by stating "the T-DNA right border sequence".
- "that can be recognized by the vir proteins" is unclear. Does this refer to (a) the left border sequence only, or (b) both the right and left border sequences? All subsequent recitations of this language are also rejected.

In claim 3,

- "modification of the left border (emphasis added)" implies one left border. Thus, the recitation of "comprises more than one left border sequence" is unclear. Does this mean that the left border is repeated? Or does it mean that a fragment of the left border is present additionally? Further, "comprises more than one left border sequence" is not a modification. Because it is unclear what is required to meet this claim limitation, this claim cannot be assessed for prior art issues.

In claim 4,

- "the T-DNA sequence" lacks antecedence;
- "a marker gene" is unclear because "gene" implies a DNA sequence that exists in nature and includes coding and noncoding regions, as well as all regulatory sequences associated with expression. Suggested language is "a polynucleotide sequence encoding a marker protein".
- "the transformant" lacks antecedent basis.

In claim 5, "including bacteria" is unclear because what other bacteria are being included for amplification is unspecified.

In claim 6,

- the spelling of "Angorbacterium" (sic) should be checked.
- This claim is an incomplete method claim, because the method requires several steps, none of which are recited. Furthermore, the recited product (transformed plant) is not produced by the final step of the method.

6. Clarification and/or correction are required.

Claim Rejections - 35 USC § 112 first paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 1- 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification,

- while being enabling for an Agrobacterium vector for plant transformation wherein the left border sequence has been modified to include one or two additional repeats of the T-DNA left border (LB) sequence,
- does not reasonably provide enablement for all modifications of the LB sequence or for any bacteria other than Agrobacterium.

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The enablement issues are "modified" DNA, and bacteria other than Agrobacterium.

With respect to the issue is DNA "modified" to do something (claim 1);

- DNA modifications include substitutions, deletions, additions and combinations thereof, of any number of nucleotides, from a single

nucleotide to an infinite number. Therefore "modified" encompasses a virtually ad infinitum number of possible combinations and permutations. One skilled in the art would be required to make an infinite number of modifications to the DNA, and without further guidance, would need to do numerous experiments, choosing from myriads of combinations of additions, substitutions and deletions to find a modified DNA capable of functioning as recited in claim 1, most of which modifications are unlikely to be operable.

- Applicant presents a working example, comprising either one or two, additional LB sequences. One skilled in the art can readily make all modifications, however one needs further guidance as to what modification would result in reducing the possibility of integration of non-T-DNA sequences into plant chromosomes, without undue experimentation.

With respect to bacteria other than Agrobacterium;

- Applicant enables Agrobacterium, and has a working example that uses Agrobacterium. However, Agrobacterium is not representative of all bacteria. Rather, the state of the art is that Agrobacterium is the only bacteria known to transform plants. Therefore it is unpredictable what bacteria other than Agrobacterium would function to transform plants, as most bacteria other than Agrobacterium have not been shown to be capable of transforming plants.

Accordingly, the claimed invention is not enabled as commensurate in scope with the claims.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1-7 are rejected under 35 U.S.C. 102(b) as being anticipated by Becker et al (Plant Molecular Biology 20: 1195-1197, 1992).

Becker teaches:

- An Agrobacterium plant transformation vector (pg 1195, 1st paragraph). Since there is no evidence of integration of any non-T-DNA segment into plant chromosomes, the vector of Becker inherently possesses the left border sequence modification set forth in the claims. Additionally, since the Agrobacterium transformation vector system utilized by Becker results in successful expression of the selectable marker in transformed plants (p1196, 1st column), the border sequences would have been recognized by the vir proteins of Agrobacterium. Becker also teaches a T-DNA region between the border sequences, insertion of the selectable marker, and the replication origin (p 1196, Figure 1, and 2nd column).

- The invention of claim 3 is also anticipated by Becker, since Becker teaches the modified LB, and the limitation of "comprises more than one left border sequence" is given no weight, for the reasons set forth in the 112-second paragraph rejection above.

Accordingly, Becker teaches the claimed invention as commensurate in scope with the claims.

REMARKS

11. No claim is allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Georgia L. Helmer whose telephone number is 703-308-7023. The examiner can normally be reached on 8:30 - 5:00. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Amy Nelson can be reached on 703-306-3218. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Georgia L. Helmer PhD
Patent Examiner
Art Unit 1638
April 18, 2002

Phuong Bui 4/19/02
PHUONG T. BUI
PRIMARY EXAMINER